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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

ATTTORNEY'S DOCKET NUMBER 3123 US0P CER 1.5)

CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE DATÉ CLAIMED PCT/JP2003/014793 November 20, 2003 November 22, 2002 TITLE OF INVENTION IMIDAZOLE DERIVATIVES, THEIR PRODUCTION AND USE APPLICANT(S) FOR DO/EO/US Keiji KUBO; Takanobu KUROITA; Yasuhiro IMAEDA; Masaki KAWAMURA Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). 6. V An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). has been previously submitted under 35 U.S.C. 154(d)(4). 7. V Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. Cited References An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. 🔽 A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

20.

Other items or information:

Page 1 of 2

Return Postcard; Certificate of Express Mailing; Cover Page International Application; Forms PcT/IB/301, 304, 306, 308, 332; ISR

JC14 Rec'd PCT/PTO 17 MAY 2005

PTO-1390 (Rev. 12-2004)
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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) INTERNATIONAL APPLICATION NO. ATTORNEY'S DOCKET NUMBER PCT/JP2003/014793 3123 US0P The following fees are submitted: a) Basic national fee......\$300.00 c) Search fee.....\$500.00 \$ 1,000.00 **TOTAL OF ABOVE CALCULATIONS =** \$1000.00 Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. Total Sheets Extra sheets Number of each additional 50 or fraction RATE thereof (round up to a whole number) - 100 = /50 = x \$250.00 492 392 2,000.00 Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)). CLAIMS NUMBER FILED NUMBER EXTRA RATE Total claims - 20 = 34 \$50.00 14 700.00 Independent claims 2 - 3 = \$200.00 0 0 MULTIPLE DEPENDENT CLAIM(S) (if applicable) \$360.00 **TOTAL OF ABOVE CALCULATIONS =** 3,700.00 Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced 3,700.00 Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)). TOTAL NATIONAL FEE = \$ 3,700.00 Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property TOTAL FEES ENCLOSED = 3,700.00 Amount to be \$ refunded: Amount to be 3,700.00 charged: a. 🔲 A check in the amount of \$ to cover the above fees is enclosed. Please charge my Deposit Account No. 500799 in the amount of \$ 3,700.00 to cover the above fees. A duplicate copy of this sheet is enclosed. c. 🔽 The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit t Account No. 500799 . A duplicate copy of this sheet is enclosed. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37,8FR 1.12/(a) or (b)) must be filed and granted to restore the International Application to pending status. SEND ALL CORRESPONDENCE TO: Mark Chao, Ph.D., JD SIGNATURE Takeda Pharmaceuticals North America, Inc Mark Chao, Ph.D., JD 475 Half Day Road NAME Lincolnshire, IL 60069 USA 37,293 (847)383-3372 fax (847)383-3409 REGISTRATION NUMBER For Customer No. 23,115

FORM PTO-1390 (REV. 12-2004)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:

Based on PCT/JP2003/014793

Filed:

Intl. Filing 20 NOVEMBER 2003

1st Inventor:

Keiji KUBO

For:

Imidazole Derivatives, Their Production and Use

Atty. Dkt. No.

3123 US0P

Art Unit:

tba

Examiner:

tba

Allowed:

Batch:

Paper No.:

CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10

USPS EXPRESS MAIL LABEL. No. EV 524904375 US

DATE IN:

May 17, 2005

Itemized Papers/Items:

- 1. This Certificate of Express Mailing and Return Postcard (2 pages)
- 2. Transmittal Letter for Filing under 35 USC 371 (2 pages X 2)
- 3. Specification total pages (492) including Claims 1-32 (pages 480-491, and Abstract (1 page)
- 4. Copies of Forms PCT/IB/ 301,304, 306, 308, 332 (5 pages)
- 5. Copy of Cover Page International Application (WO 2004/048363) (1 page)
- 6. Copy of International Search Report (3 pages)
- 7. Preliminary Amendment (14 pages)

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

MAIL STOP PCT P.O. BOX 1450

Commissioner for Patents Alexandria, VA 22313-1450

on this date, May 17, 2005

Dated: 5/17/05

Gail L. Winokur

Takeda Pharmaceuticals North America, Inc. Intellectual Property Department 475 Half Day Road Lincolnshire, IL 60069 USA